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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/730,749	Applicant(s) TOMASSO ET AL.	
	Examiner NATALIA LEVKOVICH	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/26/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 08/26/2008 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a), upon further consideration. The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Therefore, the measurement device, the incubator, the test element holders, the test element recess containing test element holders holding test elements, the test element holder containing cup-shaped wells *and* test strips, as well as the removable holder comprising immunoassay test reaction container, must be clearly shown and indexed, or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 1 and 4 are objected to because they are substantial duplicates of one another. Note that when two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 3-14 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is not commensurate in scope with the specification because it recites a transport system carrying a removable holder which includes a number of components arranged "on the same line of travel ...when the removable holder is transported" by the transport system (this recitation covering any types of transport systems, including those which can change their location (for example, carts on wheels) and can have "lines of travel" of any shape); while the specification only describes the transport system which includes two concentric rotors mounted on a stationary center of rotation, which is a significantly narrower scope than that of the claim. Additionally, the "line of travel" lacks antecedency. The claim further defines that the removable holder is configured to arrange the probe tip dispenser, fluid supply section and test element recess "on the same line of travel to intersect the liquid dispense or aspirating station (when the removable holder is transported to the station by the transport system). It is unclear whether or not this means that the station must be located over at least

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one of the rotors and that the above cited components must be arranged on the removable holder serially and along a circular line concentric with the rotors. Furthermore, Examiner maintains that it is unclear what structural features of the removable holder containing would allow it “to contain the test element recess such that a test element can be acted upon by the liquid dispense or aspirating station, while the test element is in the recess”. Therefore, the claim is incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3-6, 10-11 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Clark et al. (US 6190617).

With respect to claims 1, 3-4, 6, 10-11 and 13, Clark discloses an automated analyzer comprising, as shown in Figure 4A, concentrically arranged carousels 36, 32 [‘transport system’, ‘first and second rotors’] and stationary probe 6 [‘liquid dispense or aspirating station’]. The carousels carry various types of ‘removable holders’, such as a test sample container segment assembly 600

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(see Figure 36) having recesses 606 ['test element recesses', probe tip dispensers', 'fluid supply sections'] capable of holding probe tips, fluids, containers with samples and/or reagents ['test elements'], or the like. The shape of the segment assemblies 600 corresponds to the shape of the rotors, and is clearly configured for arranging the components accommodated by the rows of recesses 606 such, that the components would be on the same line of travel during rotation. The system further includes 'measurement devices', such as modules 69, 71 and photomultiplier tube which measure the chemiluminescent signal of the samples (Figures 16 and 17). As to the size of the analyzer, Clark discloses "compact, table-top analyzers" in column 2, lines 57-58.

Referring to claim 5, Clark teaches that "the reaction vessel containing the test sample and one or more reagents is transferred to a process carousel wherein controlled environment conditions exist ['incubator' – Ex"] (Col.16, lines 5-10).

Regarding claim 11, the test sample container segment assembly of Clark can contain a variety of sample containers ['different test elements'].

Allowable Subject Matter

8. Claims 7-9, 12 and 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art does not teach, or fairly suggest waste collection containers and centrifuge modules located on the rotors, as recited in claims 7-9.

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The prior art does not teach, or fairly suggest a first holder including dry-slide test elements and a second holder including an immunoassay test reaction container, as recited in claim 12, or a test element holder containing cup-shaped wells and test strips, as recited in claim 14.

See the appropriate paragraphs of the 06/21/2007 Office Action.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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10. Claims 1 and 3-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 of co-pending Application No 10/436537. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the instant claims are entirely within the scope of the co-pending application.

Claims 1 and 3-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12 of co-pending Application No 10/403266. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the instant claims are entirely within the scope of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments filed 08/26/2008 have been fully considered but they moot in view of the new grounds of rejection.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is

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571-272-2462. The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797